K112880

JAN 31 2013

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

SUMMARY PREPARED: January 25, 2013

1.1 SUBMITTER'S NAME, ADDRESS, TELEPHONE NUMBER, CONTACT PERSON, AND DATE SUMMARY PREPARED

APPLICANT:
Freedom Meditech, Inc.
10455 Pacific Center Court
San Diego, CA 92121, USA
Tel: (858)-638-1433

Contact Person:
Craig H. Misrach
Chairman & CEO

1.2 NAME OF DEVICE, INCLUDING TRADE NAME AND CLASSIFICATION NAME

TRADE NAME: ClearPath DS-120® Lens Fluorescence Biomicroscope

COMMON NAME: ClearPath DS-120® Lens Fluorescence Biomicroscope

CLASSIFICATION NAME: Ophthalmoscope (Class II)

DEVICE CLASSIFICATION: 21 CFR 886.1570

PRODUCT CODE: MYC

PREDICATE DEVICE: Optos PIC P200MAAF Ophthalmoscope, K102492

1.3 SUBSTANTIALLY EQUIVALENT TO

510(K) NUMBER	TRADE OR PROPRIETARY OR MODEL NAME	MANUFACTURER
K102492	PIC P200MAAF OPHTHALMOSCOPE	OPTOS

K112880

1.4 DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION

1.4.1 MAJOR COMPONENTS

The major functional components of the ClearPath DS-120® Lens Fluorescence Biomicroscope are an optics unit and a laptop personal computer.

The only components that contact the patient are a manually adjustable headrest (in/out) and a motorized adjustable chin rest (up/down).

The adjustable optics window does not contact the patient.

1.4.2 PRINCIPLES OF OPERATION

The patient is positioned with the forehead centered on the headrest. The eye is illuminated by near-infrared lights and observed by an IR sensitive video camera. An image of the eye is displayed on the computer screen to assist the operator in the alignment of the patient's eye.

The headrest is adjusted manually so that the eye is in focus in the camera image that is visible on the computer screen. The patient is instructed to look at a red blinking fixation light. The operator can adjust the chin rest and optics window positions to enable the patient to sit comfortably with the fixation target properly positioned. The software includes an automatic tracking program for positioning the pupil.

The blue light source and the collection optics are confocally aligned within a volume of measurement that is scanned through the lens. In the eye, this blue light is scattered by elastic (Rayleigh scattering) and inelastic (fluorescent) interactions with lens proteins. Filters in the collection optics reject light from the positioning lights and isolate blue and green light signals, which are detected by a highly sensitive photomultiplier and sent to an A/D converter and then to the computer.

Under software control, the volume of measurement is scanned through the lens and back. Computer software records both scattered and fluorescent light and computes the average of the ratio of lens autofluorescence to scattered light in the central portion of the lens. Software rejects scans that are outside of physiological limits or have anomalies due to eye blinks, or to excessive differences between the forward and reverse scans. For valid scans, the fluorescence ratio is reported on the screen and can be printed for the patient and/or for the patient's file.

1.4.3 MAINTENANCE AND CALIBRATION

There are no user serviceable parts or adjustments in the optics unit. The system self-tests when it is turned on. There is no maintenance required from the clinician other than cleaning the head and chin rest and optics window, as described in the Instruction for Use.

K112880

1.5 INDICATION FOR USE

The ClearPath DS-120® Lens Fluorescence Biomicroscope is indicated for use to detect autofluorescence of the crystalline lens.

1.6 PREDICATE DEVICE COMPARISON TABLE

	ClearPath DS-120® Lens Fluorescence Biomicroscope	P200MAAF Ophthalmoscope (K102492)
1. Intended Use	To examine the eye via detection of autofluorescence from ocular structures	To examine the eye via detection of autofluorescence from ocular structures
2. Indications for Use	The ClearPath DS-120® Lens Fluorescence Biomicroscope is indicated for use to detect autofluorescence of the crystalline lens.	The P200MAAF scanning laser ophthalmoscope is intended to be used as a wide field and retinal fluorescence and autofluorescence imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases or disorders that manifest in the retina.

	ClearPath DS-120® Lens Fluorescence Biomicroscope	P200MAAF Ophthalmoscope (K102492)
3. Method of operation	The instrument consists of an optoelectronic unit and a computerized system of data acquisition and processing. The instrument is a scanning biomicroscope that uses a low power blue LED beam to scan in one dimension (depth) over the lens. The returned light is detected and used to generate a digital image with a computer or electronic imaging device.	The instrument consists of an optoelectronic unit and a computerized system of data acquisition and processing. The P200MAAF is a conventional scanning laser ophthalmoscope that uses low power blue, red and green laser beams to scan in two dimensions over the retina. The reflected (or returned) light is detected and used to generate a digital image with a computer or electronic imaging device.

K112880

	ClearPath DS-120® Lens Fluorescence Biomicroscope	P200MAAF Ophthalmoscope (K102492)
	The device uses a blue LED as a light source that is scanned by a deflection system in one axis (depth) to generate a one-dimensional image.	The device uses blue, green, and red lasers as light sources that are scanned by a deflection system in two axes across the retina to generate an image.
	The scanning of the beams on one axis is done by a stepper motor driven displacement of a volume of measurement at the intersection of focused illumination and collection optics.	The scanning of the beams on the two axes is done using a rotating polygon for the fast vertical scan and a motor driven mirror for the slower horizontal scan.
	The generation of the image is performed using light detectors, the output of which is digitized, and the data collected in a computer for reconstruction, display, and storage.	The generation of the image is performed using light detectors, the output of which is digitized, and the data collected in a computer for reconstruction, display, and storage.
	An alignment system helps ensure that the patient's eye is correctly positioned.	An alignment pattern helps ensure that the patient's eye is correctly positioned.
	The returned light then travels back through the device to a rotating filter wheel and a discrete detector that converts the light to an electrical signal (effectively a blue and green channel).	The returned light then travels back through the device to an array of discrete detectors that converts the light to an electrical signal (red, green and blue channels).
	This electrical signal is digitized and used to build up an electronic picture in a computer and displayed on a computer display.	This electrical signal is digitized and used to build up an electronic picture in a computer and displayed either on a cathode ray tube or a liquid crystal display.
	The signal strength varies as the beam is scanned through the lens, allowing an image to be created and recorded, revealing the variation in its constituent material and structures.	The signal strength varies as the laser beam is scanned across the eye, allowing an image to be created and recorded, revealing the variation in its constituent material and structures.

K112880

	ClearPath DS-120® Lens Fluorescence Biomicroscope	P200MAAF Ophthalmoscope (K102492)
4. Exposure parameters	Illumination is provided by a blue LED and filter, three 880 nm LEDs, and a red fixation target. Compliance to electrical safety (including EMC), light emitting products, programmable devices and biocompatibility standards are met.	Illumination is provided by red and blue lasers. Compliance to electrical safety (including EMC), light emitting products, programmable devices and biocompatibility standards are met.
5. Data Collection and Display	Image analysis software is integrated with the data collection software. The images produced are displayed as separate blue channel and green channel images. The green channel image shows the natural fluorescence (autofluorescence) of the lens of the eye. Software detects the lens two images of the lens (forward and reverse scans), and integrates the blue and green signal intensities. The ratio of green and blue integrated measurements is displayed on the computer monitor.	The images can be exported from the device as "tiff" image files for analysis on a personal computer. The images produced can be displayed as separate green channel and a red channel images. In one imaging mode, the eye is illuminated using the green laser, and a red channel image shows the natural fluorescence (autofluorescence) of the eye. In another mode, only the blue laser illuminates the retina and the green channel fluorescence is recorded. Device software is designed to display images. The tiff files could be read by general purpose image analysis software (e.g., NIH Image), which would enable blue and green image intensities to be measured in user-selected image areas.
6. Flammability of Materials	The low power LEDs do not present ignition hazard. Materials are standard optical and electronic components.	Not available

	ClearPath DS-120® Lens Fluorescence Biomicroscope	P200MAAF Ophthalmoscope (K102492)
7. Maximum temperature of parts of the device held by the operator or accessible to the patient	All accessible parts operate near ambient temperature.	Not available
8. Brightness controls	Brightness is controlled by the instrument.	Not available

Both instruments have similar configurations and principles of operation. Light with selected wavelength ranges is focused on eye structures and the returned light is measured at selected wavelengths.

The Optos P200MAAF uses three lasers for illumination. The ClearPath DS-120 Lens Fluorescence Biomicroscope uses an eye-safe blue LED for illumination that is focused on the lens. No new safety issues are raised by this difference as both devices are within optical radiation safety limits.

Both instruments scan the illumination beam and record an image. The Optos scans in two directions on the retina surface. The ClearPath DS-120 Lens Fluorescence Biomicroscope scans in one direction through the depth of the lens to generate a depth profile (a one-dimensional image).

Optical Equivalency and Radiation Safety

Scanning laser ophthalmoscopes using Class 1 lasers are exempt from this requirement. The low power LED light source in this instrument does not raise new safety questions. Optical safety is further discussed below.

1.7 Brief Summary Of Nonclinical And Clinical Tests And Results

1.7.1 Bench

Bench testing has been performed for radiation safety and for linearity of the photodetector response.

Optical Radiation Safety

The patient is exposed to three optical sources. Three of the optical sources, the blue LED probe, the red blinking LED fixation light, and the three near-infrared illumination LEDs for pupil positioning, are actively used while the patient interacts with the instruments.

The ClearPath DS-120® Lens Fluorescence Biomicroscope has been independently reviewed for optical radiation hazard. The instrument operates at all wavelengths and

emission levels that would not produce any ocular injury – even within foreseeable misuse conditions.

DETECTOR LINEARITY

To demonstrate linear photometer response in the clinically relevant dynamic range of the signal, mixtures of coumarin (a fluorescent material) and microspheres (scattering) were prepared and dilutions of this mixture were measured by placing a cuvette with the mixtures in the optical path. The detector response vs. dilution factor was linear in both the fluorescence and scatter channels. We also compared the detector response observed in this experiment with the range of detector responses observed in our clinical study to confirm that these linear detector responses correspond to the dynamic range observed during clinical use.

1.7.2 Clinical Precision Study

SUMMARY OF PROTOCOL

A clinical study was performed to evaluate the repeatability and reproducibility of the ratio of the lens fluorescence and scattering response of human crystalline measured by the ClearPath DS-120. This was a prospective single-site study with a recruitment goal of twenty one (21) participants minimum to be enrolled based on the study eligibility criteria. Subjects who signed an informed consent form and met all the inclusion and exclusion underwent a ClearPath DS-120 examination. Three operators (A, B, and C) and three units of ClearPath DS-120 (1, 2, and 3) were included in the study.

In order to evaluate the inter-operator variability, each of three operators used Unit 1 to take three successful lens fluorescence measurements on each test subject. The three Operator/Device configurations for the inter-operator variability are A/1, B/1, and C/1. Therefore nine successful measurements were collected on each test subject for the inter-operator evaluation.

In order to evaluate the inter-device variability, Operator A used each of the three ClearPath DS-120 units to take three successful lens fluorescence measurements on each test subject. The three Operator/Device configurations for the inter-device variability are A/1, A/2, and A/3. Therefore nine successful measurements were collected on each test subject for the inter-device evaluation.

The measurement order of the five configurations was randomized. Subjects were repositioned between all scans.

K112880

RESULTS

Demographics of the enrolled study population are shown in the table below. The gender of study subjects was reasonably distributed and the age of the study subjects ranged from 21 years to 68 years, with a median age of 46 years. The range of Lens Fluorescence measurements obtained from these 27 precision study subjects was 0.07 to 0.33.

DEMOGRAPHIC INFORMATION

	n/N	%
Gender		
Male	14/27	51.9%
Female	13/27	48.1%
Age (year)		
N	27	
Mean	43.9	
SD	14.9	
Median	46.0	
Min	21	
Max	68	
20 - 29	6/27	22.2%
30 - 39	5/27	18.5%
40 - 49	6/27	22.2%
50 - 59	5/27	18.5%
60 - 69	5/27	18.5%
Ethnicity		
Asian/Pacific Islander	8/27	29.6%
Caucasian	16/27	59.3%
Hispanic	1/27	3.7%
Multi-Race	2/27	7.4%

This table summarizes the precision data from each device and from all three devices combined.

PRECISION SUMMARY

Statistics	All Devices (3)	Devices 1	Devices 2	Devices 3
Number of Subjects	27	27	27	27
Number of Successful Scans	405	243	81	81
Mean	0.17899	0.18029	0.17383	0.18025
Standard Deviation	0.04718	0.04669	0.04865	0.04741
Repeatability SD[1]	0.01034	0.01015	0.01170	0.01005
Repeatability %CV[1]	5.779	5.630	6.731	5.576
Reproducibility SD[2]	0.01153	—	—	—
Reproducibility %CV[2]	6.443	—	—	—

1 Repeatability SD = Estimate of the standard deviation among measurements taken on the same eye using the same operator and device in the same testing session with repositioning.
Repeatability %CV = Repeatability SD ÷Mean. ×100.

2 Reproducibility SD = Estimate of the standard deviation among measurements taken on the same eye using different operators and devices, including repeatability.
Reproducibility %CV = Reproducibility SD ÷Mean. ×100.

No adverse events were observed during the study.

STUDY CONCLUSION

This clinical precision study showed the device to be safe and characterized well the variability of the measurements provided by the Clear Path DS-120 device for the range of 0.07-0.33. The variability of the autofluorescence measurements provided by the ClearPath DS-120 device shows the device is fit for its purpose as a measurement tool. The purpose of this study was not to establish the diagnostic or prognostic utility of the device; therefore, these results do not imply any correlation with a specific clinical diagnosis or prognosis.

1.8 BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

As described in this 510(k) Summary, all testing deemed necessary was conducted on the ClearPath DS-120® Lens Fluorescence Biomicroscope to ensure that the device is safe and effective for its intended use when used in accordance with its Instructions for Use.

Minor differences between the Indications for Use statement and that of the predicate device do not alter the intended diagnostic effect or affect safety or effectiveness for the intended use.

The minor differences in technical characteristics between the ClearPath DS-120® Lens Fluorescence Biomicroscope and the predicate Optos P200MAAF ophthalmoscope do not affect safety or effectiveness for the intended use. The physics of the measurement and basic system functions are the same as the Optos P200MAAF. The descriptive rationale for substantial equivalence is supported by bench and clinical testing as described above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

January 31, 2013

Freedom Meditech, Inc.
% Mr. Craig H. Misrach, MBA, CPA
Chairman & CEO
10455 Pacific Center Court
San Diego, CA 92121

Re: K112880
Trade/Device Name: ClearPath DS-120® Lens Fluorescence Biomicroscope
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: MYC
Dated: January 25, 2013
Received: January 28, 2013

Dear Mr. Misrach:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Opthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): _____K112880_____

Device Name: ClearPath DS-120® Lens Fluorescence Biomicroscope

Indications for Use:

The ClearPath DS-120® Lens Fluorescence Biomicroscope is indicated for use to detect autofluorescence of the crystalline lens.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices
510(k) Number K112880